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43354 MESCHKOW	7590 10/02/2007 & GRESHAM, P.L.C.	EXAMINER		
5727 NORTH	SEVENTH STREET, SUIT	REIDEL, JESSICA L		
PHOENIX, AZ	85014		ART UNIT	PAPER NUMBER
•			3766	
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			10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		I	Application	No.	Applicant(s)			
Office Action Summary			์ 1ั้ง/784,088		SKIBA, JEFFRY B.			
			Examiner		Art Unit			
		I .	Jessica L. F		3766			
<i> The</i> Period for Re	e MAILING DATE of this commur ply	nication appe	ears on the o	over sheet with the c	orrespondence ac	idress		
WHICHEV - Extensions after SIX (6) - If NO period - Failure to re Any reply re	ENED STATUTORY PERIOD F YER IS LONGER, FROM THE N of time may be available under the provisions MONTHS from the mailing date of this common of for reply is specified above, the maximum simply within the set or extended period for reply proceived by the Office later than three months and term adjustment. See 37 CFR 1.704(b).	MAILING DATES of 37 CFR 1.136 munication. tatutory period will will, by statute, c	TE OF THIS (a). In no even I apply and will of cause the applic	S COMMUNICATION , however, may a reply be tin expire SIX (6) MONTHS from ation to become ABANDONE	V. nely filed the mailing date of this o D (35 U.S.C. § 133).			
Status								
1)⊠ Res	ponsive to communication(s) file	ed on 18 Mag	y 2007.			•		
• ——	•—		s action is non-final.					
3) Sinc								
Disposition o	f Claims	•						
4a) 0 5)∭ Clai 6)⊠ Clai 7)⊠ Clai	Claim(s) 1-19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) 1-9,12-15 and 17-19 is/are rejected. Claim(s) 10,11 and 16 is/are objected to. Claim(s) are subject to restriction and/or election requirement.							
Application F	'apers							
10)⊠ The Appl Rep	specification is objected to by the drawing(s) filed on 19 February licant may not request that any objected that any objected to a declaration is objected the specific objection of the specific objection objecti	<u>2004</u> is/are: ection to the di g the correction	: a)⊠ acce rawing(s) be on is required	held in abeyance. Se I if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 C	FR 1.121(d).		
Priority unde	r 35 U.S.C. § 119							
12) Ackr a) Al 1. 2. 2. 3.	nowledgment is made of a claim b) Some * c) None of: Certified copies of the priority Certified copies of the priority	y documents y documents s of the priorit onal Bureau	have been have been ty documer (PCT Rule	received. received in Applicat its have been receive 17.2(a)).	ion No ed in this Nationa	l Stage		
2) Notice of D 3) Information	References Cited (PTO-892) Draftsperson's Patent Drawing Review (n Disclosure Statement(s) (PTO/SB/08) s)/Mail Date			4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	atė			

U.S. Patent and Trademark Office PTOL-326 (Rev. 08-06)

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DETAILED ACTION

1. The Examiner notes that the Office mistakenly mailed an Office Action on August 7, 2007 to an incorrect address. It appears that the Office received Change of Address/Power of Attorney notices on both December 12, 2006 and February 21, 2007. Accordingly, the Office Action of August 7, 2007 is withdrawn and is replaced with the enclosed.

Acknowledgement of Amendment

2. Acknowledgement is made of Applicant's Amendment, which was received by the Office on May 18, 2007. Claims 20-34 have been cancelled. Claims 1-19 are pending.

Drawings

3. In view of the response filed May 18, 2007, the objections applied to the Drawings in the Office Action of March 12, 2007 have been withdrawn.

Allowable Subject Matter

- 4. The indicated allowability of claims 1-9, 12-15 and 17-19 is withdrawn in view of the newly discovered reference(s) to Conn et al. (U.S. 2002/0004640) (herein Conn), Axelgaard (U.S. 6,038,485), Tapper (U.S. 4,211,222) and Watanabe (U.S. 6,248,449). Rejections based on the newly cited reference(s) follow.
- 5. Claims 10-11 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Objections

6. In view of the response filed May 18, 2007, the objections applied to the Claims in the Office Action of March 12, 2007 have been withdrawn.

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Claims 1, 6 and 9 are objected to because of the following informalities: there appears to exist minor typographical errors in the claims. As to Claim 1, line seven, the Examiner suggests changing "includes a first elements; and" to read, ""includes a first element; and" instead in order to correct a grammatical error. As to Claim 6, line six, the Examiner suggests changing "used in the first named mixing step;" to read, "used in a first named mixing step;" instead in order to avoid an antecedent basis problem. As to Claim 9, line six, the Examiner suggests changing "dog" to read, "dot" instead. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. In view of the response filed May 18, 2007, the 35 U.S.C. 112, second paragraph rejections applied to the Claims in the Office Action of March 12, 2007 have been withdrawn.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Conn. As to Claim 1, Conn expressly discloses a method comprising making a surface pattern of spaced, dissimilar electrodes 630, 631, 632 by printing a first ink onto a primary surface of a substrate, read as an article 634 to form a first pattern/design (i.e. a first pattern or design of electrodes 630, 632) comprising at least one discrete design and printing a second ink onto the primary surface of the article 634 to form a second pattern (i.e. a second pattern or design of electrode 631) that is interspersed throughout the first pattern (see Conn Fig. 6). The first printed

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ink pattern includes a first element of silver and the second printed ink pattern includes a second element of platinum (see Conn page 3, paragraphs 47-48, pages 5-6, paragraphs 68-81 and pages 8-10, paragraphs 95-112). Conn expressly discloses that the first and second inks are dried into place by passing through convention ovens, thus the silver of the first ink and the platinum of the second ink do not amalgamate with each other (see Conn page 15, paragraphs 159-161).

- 11. As to Claim 4, Conn expressly discloses that the printing of the inks into the spaced and patterned electrodes is performed via screen-printing. It is inherent that screen-printing is performed using a screen-printing apparatus (see Conn page 3, paragraphs 47-48, pages 5-6, paragraphs 68-81 and pages 8-10, paragraphs 95-112).
- 12. As to Claim 5, Conn expressly discloses that the second pattern/design (i.e. electrode 631) is interspersed throughout the first pattern/design (i.e. electrodes 630, 632) such that there is at least a half a millimeter (i.e. 0.5 inches) spacing between the silver and platinum elements within each ink that make up the patterns (see Conn Fig. 8B and page 15, paragraphs 159-161).
- 13. As to Claim 8, Conn expressly discloses the claimed invention as previously discussed and further specifies that at least one repetition of the first pattern/design 630, 632 lies substantially adjacent the second pattern/design 631 on the primary surface of the article 634 (see Conn Figs. 3-5, Fig. 7 and Fig. 8B). Both inks used by Conn include a mixture of a metal species (i.e. silver or platinum) and a polymer binder, such as a biocompatible poly acrylic binder. The metal species of the first ink pattern 630, 632 includes silver and the metal species of the second ink pattern 631 includes platinum (see Conn page 3, paragraphs 47-48, pages 5-6, paragraphs 68-81, pages 8-10, paragraphs 95-112 and page 15, paragraphs 159-161).

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- 14. As to Claim 13, in addition to the arguments previously presented, the Examiner makes specific reference to Conn Fig. 6 where it is shown that the first ink pattern/design 630, 632 is comprised of a visible symbol of a crescent or curved shape. Conn further specifies that the first ink pattern/design may be printed onto the primary surface of article 634 "in any suitable pattern or geometry" (see Conn page 10, paragraph 111).
- 15. As to Claim 14, Conn discloses the claimed invention as previously discussed and further specifies that article 634 may include a flexible, read as pliable nonconductive surface. The pliable materials for article 634, discussed at page 10, paragraph 111 of Conn, are considered to be synonymous with "dressing materials", since polyester and polyimide are commonly used in biomedical and/or biocompatible dressings for dermal applications. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The dressing material of article 634 is capable of being applied to an area of damaged tissue since it maintains operative contact (via flow paths) with skin or mucosal surface (see Conn pages 10-14, paragraphs 115-155).
- Axelgaard discloses a method comprising making a surface pattern of spaced dissimilar electrodes (see Axelgaard Fig. 7) comprising printing a first ink onto a primary surface 20 of a flexible conductive film or sheet, read as an article 110 to form a first pattern comprising at least one discrete design (i.e. a spot) and printing a second ink onto the primary surface to form a second pattern that is interspersed throughout the first pattern such that elements of the first ink do not amalgamate with those of the second. The Examiner considers the first row of each of the

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first and third columns of spots 106 depicted in Axelgaard Fig. 7 to be the first pattern and the first row of the middle column of spots 106 to be the second pattern. Axelgaard further discloses that the conductive inks used to print each spot may include any suitable blend of inks each including a first and second element of a conductive species (i.e. carbon or metals) and further that it may be desirable for some ink spots to have "varied conductivity" in order to tailor the current through the surface pattern of conductive electrodes. Electrode ink spots 106 having "varied conductivity" are not the same and are thus "dissimilar" (see Axelgaard column 4, lines 14-56 and column 6, lines 17-36).

Claim Rejections - 35 USC § 103

- 17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 18. Claims 12 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn. As to Claim 12, Conn discloses the claimed invention except does not expressly disclose that the first ink pattern/design include a line that is approximately 2.5 mm +/- 2 mm or that the spacing be approximately 1.5 mm +/- 1 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the first ink pattern/design and the spacing, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. In re Aller, 105 USPQ 233.

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- 19. As to Claims 17-18, Conn discloses that the first element of the first ink may include silver particulates, read as powders (see Conn page 9, paragraphs 109-112 and page 15, paragraphs 159-161). Conn discloses the claimed invention as previously discussed except that it is not specified that the second element of the second ink include zinc powder. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use zinc particulates, or powders, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).
- 20. Claims 2-3, 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conn in view of Watanabe. As to Claims 2-3 and 19, Conn discloses the claimed invention as previously discussed except that it is not specified that the silver is ground into a first powder and then mixed with a binder of either poly acrylic or epoxy to form the conductive ink for screen printing the electrode patterns on the flexible article 634. Grinding a first element into a first powder and then mixing the powder with a binder are routine in forming conductive inks for screen-printing a flexible substrate is conventional and well known in the art and the Examiner cites Watanabe as being but one example. Watanabe discloses a method of making a conductive ink for screen-printing, which is inexpensive, that includes first grinding an alloy of silver and palladium into alloy spherical powders having an average diameter of 10 µm and then mixing such powders with a binder (i.e. epoxy or a poly acrylic) (see Watanabe Abstract, column 2, lines 15-67 and columns 5-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Conn in view of Watanabe such that the method includes grinding a first element into a first powder and then mixing the first powder with a binder to

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form conductive poly acrylic ink or conductive epoxy ink in order to fabricate conductive inks for screen-printing in an inexpensive manner.

- As to Claim 7, the previously modified Conn reference discloses the claimed invention as previously discussed except that it is not specified that the binder comprise at least 15 percent, by weight, of the first ink. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the binder comprise at least 15 percent, by weight, of the first ink, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, Watanabe teaches that it is desirable for the binder to comprise at least 15 percent, by weight of a conductive ink used in screen-printing in order to maintain and secure conductivity and at the same time, increase hardness of the conductive pattern printed using such an ink (see Watanabe column 5, lines 1-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the binder comprise at least 15 percent, by weight, of the first ink since it is desirable for the conductive ink to be conductive and hard as taught by Watanabe.
- 22. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conn in view of Watanabe and Siuta (U.S. 4,540,604). The previously modified Conn reference discloses the claimed invention as previously discussed except that it is not specified that the particulates of the conductive inks be first sifted in order to chose particulates having a predetermined size for mixing with the appropriate binder. The Examiner considers the use of a mesh or screen for sifting powders to be conventional and well known within the art of conductive inks, pastes, and gel formulations and cites Siuta as being but one example. Siuta teaches that when formulating a

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conductive ink for screen-printing it is preferable to use powders having particle sizes below 10 µm (see Siuta column 4, lines 15-24) and further that it is known to use a screen mesh to for sifting out particles greater than a desired size (see Siuta column 7, lines 4-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Conn in view of Watanabe such that the method includes shifting the ground powders through a mesh as taught by Siuta in order to separate one size of particles from another for use in formulating a reliable conductive ink for use in screen-printing.

- 23. Claims 5 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axelgaard. As to Claim 5, Axelgaard discloses the claimed invention as previously discussed except that it is not specified that the space that exists to the right and left of the second pattern (i.e. between the second column of spots and both the first and third column of spots 106) be at least half a millimeter. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions such that within each row of spots 106 as disclosed by Axelgaard, at least a half a millimeter of space exists between the second column of spots 106 and the first and third columns of spots 106, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. In re Aller, 105 USPQ 233.
- 24. As to Claims 17-18, Alexgaard discloses the claimed invention except that it is not specified that the inks of each spot 106 include zinc powder or silver powder. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use zinc or silver particulates, or powders, since it has been held to be within the general skill of a

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worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

- Claims 2-4, 7, 14 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable 25. over Axelgaard in view of Watanabe. As to Claims 2-4, 14 and 19, Axelgaard expressly discloses that each column of spots includes multiple rows of spots (see Axelgaard Fig. 7), thus each design is repeated to create an alternating pattern. Axelgaard discloses the claimed invention except that it is not specified how the conductive inks for each printed spot 106 are formulated. Grinding a first element into a first powder and then mixing the powder with a binder are routine in forming conductive inks for screen-printing a flexible substrate is conventional and well known in the art and the Examiner cites Watanabe as being but one example. Watanabe discloses a method of making a conductive ink for screen-printing, which is inexpensive, that includes first grinding an alloy of silver and palladium into alloy spherical powders having an average diameter of 10 µm and then mixing such powders with a binder (i.e. epoxy or a poly acrylic) (see Watanabe Abstract, column 2, lines 15-67 and columns 5-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Axelgaard in view of Watanabe such that the method includes grinding a first element into a first powder and then mixing the first powder with a binder to form conductive poly acrylic ink or conductive epoxy ink in order to fabricate conductive inks for screen-printing in an inexpensive manner.
- 26. As to Claim 7, the previously modified Axelgaard reference discloses the claimed invention as previously discussed except that it is not specified that the binder comprise at least 15 percent, by weight, of the first conductive ink. It would have been obvious to one having

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ordinary skill in the art at the time the invention was made to make the binder comprise at least 15 percent, by weight, of the first ink, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Furthermore, Watanabe teaches that it is desirable for the binder to comprise at least 15 percent, by weight of a conductive ink used in screen-printing in order to maintain and secure conductivity and at the same time, increase hardness of the conductive pattern printed (see Watanabe column 5, lines 1-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the conductive ink composition of Axelgaard such that the binder comprises at least 15 percent, by weight, of the conductive ink since it is desirable for conductive ink to be both conductive and hard as taught by Watanabe.

27. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Axelgaard in view of Watanabe and Situa. The previously modified Axelgaard reference discloses the claimed invention as previously discussed except that it is not specified that the particulates of the conductive inks be first sifted in order to chose particulates having a predetermined size for mixing with the appropriate binder. The Examiner considers the use of a mesh or screen for sifting powders to be conventional and well known within the art of conductive inks, pastes, and gel formulations and cites Siuta as being but one example. Siuta teaches that when formulating a conductive ink for screen-printing it is preferable to use powders having particle sizes below 10 µm (see Siuta column 4, lines 15-24) and further that it is known to use a screen mesh to for sifting out particles greater than a desired size (see Siuta column 7, lines 4-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify

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the method of Axelgaard in view of Watanabe such that the method includes shifting the ground powders through a mesh as taught by Siuta in order to separate one size of particles from another for use in formulating a reliable conductive ink for use in screen-printing.

28. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Axelgaard in view of Watanabe and Tapper. The previously modified Axelgaard reference discloses the claimed invention as previously discussed except that it is not specified that the method include fixing an absorbent cloth layer to the back of the pliable dressing material of article/substrate 110.

Tapper, however, teaches that it is well known in the art of skin electrodes for a porous intervener material 4 to typically be fixed in contact with the under side of an electrode portion 1 in order to prevent burning the skin. Material 4 is absorbent for burn particles emanating from the electrode portion 1 (see Tapper Fig. 1, column 2, lines 64-66 and column 4, lines 37-45). Therefore, it would have been obvious to one having ordinary skill in the art to modify the apparatus of Axelgaard in view of Watanabe such that an intervening absorbent and porous cloth layer is fixed to the back of the pliable dressing material including the electrode pattern since such a modification would prevent burning of the skin as taught by Tapper.

29. Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axelgaard in view of Watanabe and Carrier et al. (U.S. 5,352,315) (herein Carrier). As to Claim 8, and in addition to the arguments previously presented, Axelgaard discloses that each pattern/design includes a "spot", read as a visible symbol. As previously discussed, Axelgaard expressly discloses that it is desirable for some ink spots to have "varied conductivity" in order to tailor the current through the surface pattern of conductive electrode spots 106. Electrode ink

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spots 106 having "varied conductivity" are not the same and are thus "dissimilar" (see Axelgaard column 4, lines 14-56 and column 6, lines 17-36). The previously modified Axelgaard reference discloses the claimed invention as previously discussed except that it is not specified that electrodes of varied conductivity comprise conductive inks that include different metal species.

Carrier, however, teaches that it is known in the art to vary electrode impedance by changing the blend of materials used to manufacture the conductive ink (see Carrier column 9, lines 12-27). Electrode impedance is representative of how easily electricity conducts through the electrode, therefore changing its impedance in turn changes its conductivity. Carrier further teaches a variety of metal species that may be used to formulate a conductive ink to be printed on a flexible substrate in a predetermined pattern such as silver chloride, tin chloride, gold chloride and platinum chloride (see Carrier column 5, lines 22-68 and column 6, lines 1-49). It would have been obvious to one having ordinary skill in the art to modify the conductive ink of Axelgaard in view of Watanabe to include different blends of metal species as taught by Carrier. Using the known technique of varying the blended composition of the conductive ink in order to vary its impedance or conductivity to provide the variable conductivity electrode surface desired in the invention of Axelgaard would have been obvious to one of ordinary skill.

30. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Axelgaard in view of Watanabe and Carrier as applied to claim 8 above, and further in view of Tapper. As to Claim 9, the previously modified Axelgaard reference discloses the claimed invention except it is not specified that the spots of the first design have a mean diameter that is smaller than those of the second design.

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Tapper, however, teaches that when applying electrical current to the skin surface it is desirable to increase the area of the positive electrodes in relation to the negative electrodes such that the two different sizes are intermingled with one another. Taper teaches that an electrode surface configured in this manner (see Tapper Fig. 5) decreasing pain or tingling due to the passage of current (see Tapper column 2, lines 31-33, column 5, lines 55-60 and column 6, lines 1-10). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surface patterned spot electrodes of Axelgaard in view of Watanabe and Carrier such that positive electrodes having a greater surface area are intermingled with negative electrodes having a smaller surface area as taught by Tapper since such a modification would improve application of current to the skin surface.

The previously modified Axelgaard reference discloses the claimed invention as previously discussed except that it is not specified that the first design include spots having a mean diameter of 1.5 mm +/- 1 mm, the second design include spots having a mean diameter of 2.5 mm +/- 2 mm and that the spacing between the rows and columns of electrode spots be approximately 1.5 mm +/- 1 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the first ink pattern/design of spots, the dimensions of the second ink pattern/design of spots and the spacing between such spots, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable range involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

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Conclusion

31. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Muroki (U.S. 5,772,688) discloses a bio-galvanic adhesive electrode comprising an

alternating pattern of dissimilar electrodes.

32. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129.

The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

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like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/ Patent Examiner, Art Unit 3766 September 14, 2007 /Kennedy J. Schaetzle/ Primary Examiner, AU 3766 September 14, 2007